EXHIBIT BB

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SEVEN YEAR DATA FOR TEN YEAR PROLENE™ STUDY: ERF 85-219

This report contains a summary of IR, IV, GPC, OM and SEM data supporting this study.

IR and IR Microspectroscopy (D.Burkley)

IR examinations were done for all explants at all sites to verify the suture identity for each explant. For all explanted sutures recovered from all 6 sites for every dog in this study, IR data showed each suture to be correctly identified.

IR microspectroscopy was used to examine cracked areas in ETHILON, Novafil and PROLENE™ explants. IR spectra obtained for cracked PROLENE specimens (Figure A) showed possible evidence of slight oxidation (a broadened weak absorbance at about 1650 cm-1). IR spectra obtained for cracked areas of ETHILON and Novafil did not differ from uncracked areas (Figures B and C), but expected IR absorbances for oxidation would be masked by the strong carbonyl absorbances normally observed for these sutures. Figures D and E show pictures of the areas examined by IR microspectroscopy for ETHILON and Novafil.

IV and GPC (E.Muse)

Gel Permeation Chromatography (GPC) was run on PROLENE sutures explanted from dogs after seven years. The GPC data was compared to data from a current 4/0 PROLENE suture. The results indicate that there was no significant difference in molecular weight between the 4/0 PROLENE control and the seven year explants.

The following PROLENE explant samples were analyzed:

Dog 1995 - site 3 (SR33853)
Dog 2007 - sites 1 and 6 (SR34003)
Dog 2008 - site 2 (SR34066)
Dog 2019 - sites 2 and 3 (SR34180)

The GPC analysis was run on the Waters 150C GPC at 140°C using 1,2,4 trichlorobenzene as a mobile phase with Waters GPC columns. The instrument was calibrated with polypropylene standards.

Inherent Viscosity (IV) was determined on ETHILON™ and Novafil sutures explanted from dogs after seven years. The IV data[1] was compared to IV data from one and two year explants. The following results were found:

1) No significant differences were seen in IV values after one and two years.
2) Seven year IV values ranged from 75% to 93% of the one and two year IV values for ETHILON sutures.
3) Seven year IV values ranged from 75% to 90% of the one and two year values for Novafil.

The dog explant samples examined were from duplicate sites on four dogs for each time period (one, two and seven years). The IV data was determined using concentrations of 0.1 dl/g with HFIP as a solvent at 25°C.

OPTICAL MICROSCOPY and SCANNING ELECTRON MICROSCOPY (E.Lindemann)

Conclusions

- The 7 year in-vivo results generally substantiated the five year findings. They also closely correspond to the observations of explanted sutures from the dog that died prematurely after 6 years and 10.5 month implantation time.

- Degradation in PROLENE is still increasing and PVDF, even though a few cracks were found, is still by far the most surface resistant in- house made suture in terms of cracking.

- Of the eight explanted ETHILON sutures all showed heavy cracking and, in many cases, abrasion of the dyed surface layer. A decrease in the suture diameter was apparent in several cases.

- Cracks were not found in the seven Novafil explants. However a few longitudinal scratches probably due to mechanical damage and one longitudinal crack were observed.

Introduction

In November 1985 twenty-four dogs had been implanted with sets of ETHILON, PROLENE, PVDF and Novafil sutures for a ten year study. In 1990, after five years, explants from 5 beagle dogs were described in " TEN YEAR IN-VIVO STUDY SCANNING ELECTRON MICROSCOPY FIVE YEAR REPORT" by Elke Lindemann. The next explantation, after 7 years, was to start in June 1992. However, after 6 years and 10.5 months dog #1995 died prematurely. The microscopical examination of those explants was described in " TEN YEAR IN-VIVO STUDY: SCANNING ELECTRON AND LIGHT MICROSCOPY INTERIM REPORT ON DOG #1995 AFTER 6 YEARS, 10.5 MONTH, SR# 33788 and are included in the conclusion section of this report. In June of 1992 after 7 years, sutures were explanted from another set of 4 dogs. This report presents the results of the light and scanning electron microscopical examination of those explants.

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[1]SR33853, SR34003, SR34066, SR34180

Experimental

Four dogs had been implanted in November 1985 with the following 5-0 sutures:

	Site 1	Site 2	Site 3	Site 4	Site 5	Site 6
Dog 2001	PVDF	ETHILON	Novafil	PROLENE	PROLENE	Novafil
Dog 2007	PROLENE	Novafil	ETHILON	PVDF	PVDF	PROLENE
Dog 2019	Novafil	PROLENE	PROLENE	PVDF	ETHILON	ETHILON
Dog 2008	ETHILON	PROLENE	Novafil	PVDF	ETHILON	PVDF

Starting in June of this year the above dogs were sacrificed in weekly intervals. Approximately 20cm long sections of the explanted sutures were received in microscopy in glass vials which were kept refrigerated until they were examined.

Also the explanted LC 100 clip with about 2cm of each suture bundle was delivered in the same vial. The clip and the attached sutures were still deeply embedded in the surrounding tissue. These 'not cleaned' sutures were supposed to answer the question whether the process of cleaning and tissue removal might be responsible for an observed cracking. The primary concern of this study was however to examine the long pieces of explanted suture. Most of these specimens were still surrounded with some tissue, fortunately at a level low enough not to obscure examination in the light microscope under transmitted light. It was possible to examine the embedded PROLENE suture where the cracking of the suture was seen through the tissue. For this reason and time constrains the clip-attached sutures were not examined at this time.

To show that the drying and coating with a metal under vacuum, necessary for SEM examination, did not introduce cracking and other surface defects each strand of each long suture was 100% inspected in the Olympus Light Microscope in water. Oil, the usual medium for light microscopical inspection, was not chosen for this examination in order to eliminate surface changes during sample preparation. To cut down on lensing effects of the curved suture, the samples were photographed in polarized light using a 10x phase condenser with an ordinary transmitted light 20x objective (a 20x phase condenser was not available). The light diffraction introduced by the phase condenser was enough to allow an easier focusing at the focal plane of the largest diameter. Photomicrographs were prepared at 285x of areas which showed surface changes.

Strands of the suture including the above areas were then prepared for SEM observation in the JEOL JSM 840 AII by coating them under vacuum with gold to provide an electron conductive surface. Photomicrographs were prepared at 500x magnification.

Results

1) LM and SEM of PROLENE suture explants from seven implantation site.

In Figure 1A through 1D one area per site from each of the four dogs is shown in transmitted light. Out of seven sites cracking was found on PROLENE sutures from three sites. Notice the cracks observable through the still adhering tissue in Figure 1A in the suture from site 2.

In Figure 1 and 2 SEM views of areas are shown after most of the tissue had been carefully removed. Again out of seven sites sutures from three sites had areas which showed cracking.

2) LM and SEM of ETHILON suture explants from six implantation sites.

In Figure 3A through 3C sutures are shown from six different sites. Transmitted light allowed visualization of the differences between the intact dyed surface layer and the underlying colorless layers of the suture. In Figure 3A site 5 and Figure 3C site 3 the colorless area had not only lost its dyed surface layer but was abraded to such a degree that a decrease in suture diameter was found.

In Figures 3 and 4 the cracking and abrasion on sutures from all six sites, as observed with the SEM, is shown. Here also the decrease in diameter is particularly dramatic in Figure 3 site 1.

3) LM and SEM of PVDF suture explants from six implantation sites.

Figure 5A through 5C show six sites of PVDF explants as seen with the light microscope. Notice the intact surface on all the sutures.

In Figures 5 and 6 the SEM examination of the PVDF sutures is shown. Only on the suture from one site (Figure 6 site 6) some cracks are found. The surfaces of the sutures from the other five sites show some striations which could be mechanical damage, otherwise the surfaces look intact. The contaminant on the site 4 (Figure 5) suture is tissue which had not been removed completely.

4) LM and SEM of Novafil suture explants from five implantation sites.

Figure 7A through 7C show the Novafil sutures as observed with the light microscope. All surfaces from all sites look undamaged. Figure 7 and 8 show the SEM examination of these sutures. A few longitudinal scratches and cracks were found, see sites 1,2,3 (Figure 7,8). Also on the site 2 suture (Figure 8) still adhering tissue is found.

5) Degradation dependency on implantation site

To probe the question as to whether one implantation site might be more or less stressful towards the suture, a comparison was made of the six sites.

	Site 1	Site 2	Site 3	Site 4	Site 5	Site 6
Dog 1995	ETHILON cracks	PVDF	PROLENE cracks	Novafil	Novafil cracks	ETHILON cracks
Dog 2001	PVDF	ETHILON cracks	Novafil	PROLENE	PROLENE cracks	Novafil
Dog 2007	PROLENE	Novafil scratch	ETHILON cracks	PVDF	PVDF	PROLENE cracks
Dog 2019	Novafil scratch	PROLENE	PROLENE	PVDF	ETHILON cracks	ETHILON cracks
Dog 2008	ETHILON cracks	PROLENE cracks	Novafil cracks	PVDF	ETHILON cracks	PVDF cracks

The only site, in the 5 dogs of this study, from which sutures were explanted that showed no surface damage was site 4. However, of those five sutures three were PVDF and one was Novafil. Those are the sutures that showed only marginal surface changes in this study. Therefore this observation can be discounted.

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Attachment

7YEAR.DFB